



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day Comment Request; Post-Award Reporting Requirements

Including Research Performance Progress Report Collection (OD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301-435-0941 or Email your request, including your address to ProjectClearanceBranch@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Public Health Service (PHS) Post-award Reporting Requirements

Revision, OMB 0925–0002, Expiration Date 3/31/2020, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Starting in January 2020, NIH will require applicants

and recipients to address Human Fetal Tissue requirements within the SF-424 R&R and the Research Performance Progress Report (RPPR) due to Congressional ((Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2)) and Department of Health and Human Services (45 C.F.R. 46.204 and 46.206) mandates regarding human fetal tissue research.

Applicants and recipients will be required to comply with Federal and state laws concerning the acquisition of human fetal tissue (including cell lines) as well as include a concise description of the proposed characteristics of the human fetal cells/tissue outlining the procurement budget

details, and how the applicants/recipients will document the processes for how they will use the human fetal tissues and cells. Additionally, this revision will clarify information regarding an institutional commitment to ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices. The RPPR is required to be used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR required the maintenance of dual reporting processes for a period of time. Continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), exists for a small group of grantees. This collection also includes other PHS post-award reporting requirements: PHS 416–7 National Research Service Award (NRSA) Termination Notice, PHS 2271 Statement of Appointment, 6031–1 NRSA Annual Payback Activities Certification, HHS 568 Final Invention Statement and Certification, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. The PHS 416–7, 2271, and 6031–1 are used by NRSA recipients to activate, terminate, and provide for payback of a NRSA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and Federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another. Pre-award reporting requirements are simultaneously consolidated under 0925–0001 and the changes to the collection here are related. Clinical trials are complex and challenging research activities. Oversight systems and

tools are critical for NIH to ensure participant safety, data integrity, and accountability of the use of public funds. NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information in the PHS applications and pre-award reporting requirements as well as continued monitoring and update during the post-award reporting requirements will facilitate NIH's oversight of clinical trials. In addition, some of the data reported in the RPPR will ultimately be accessible to investigators to update certain sections of forms when registering or reporting their trials with ClinicalTrials.gov. *Frequency of response:* Applicants may submit applications for published receipt dates. For NRSA awards, fellowships are activated, and trainees appointed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 519,408.

Estimated Annualized Burden Hours

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
REPORTING				
PHS 416-7	12,580	1	30/60	6,290
PHS 6031-1	1,778	1	20/60	593
PHS 568	11,180	1	5/60	932
iEdison	5,697	1	15/60	1,424
PHS 2271	22,035	1	15/60	5,509
PHS 2590	243	1	18	4,374
RPPR – Core Data	32,098	1	8	256,784

Biosketch (Part of RPPR)	2,544	1	2	5,088
Data Tables (Part of RPPR)	758	1	4	3,032
Trainee Diversity Report (Part of RPPR)	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report)	6,420	1	4	25,680
Publication Reporting	97,023	1	5/60	8,085
Final RPPR – Core Data	18,000	1	10	180,000
Data Tables (Part of Final RPPR)	758	1	4	3,032
Trainee Diversity Report (Part of Final RPPR)	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of Final RPPR, includes inclusion/enrollment)	3,600	1	4	14,400
PHS 374	479	1	30/60	240
Final Progress Report	2,000	1	1	2,000
SBIR/STTR Phase II Final Progress Report	1,330	1	1	1,330
Reporting Burden Total				519,033
RECORDKEEPING				
SBIR/STTR Life Cycle Certification	1,500	1	15/60	375
Grand Total	220,983	220,983		519,408

Date: April 5, 2019.

Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.

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